We claim:

1. A diagnostic kit comprising primers or probes that amplify or hybridize with 5T4 RNA extracted from a bodily fluid or cDNA prepared therefrom.

2. A diagnostic kit according to claim 1 further comprising reagents for detectably-labeling 5T4 RNA extracted from a bodily fluid or cDNA prepared therefrom.

3. A method of detecting 5T4 RNA in blood plasma or serum in blood plasma or serum from a human for detecting, diagnosing, monitoring, treating, or evaluating a neoplastic disease comprising cells that express 5T4 RNA, the method comprising the steps of:

a) extracting RNA from blood plasma or serum;

b) amplifying a portion of the extracted RNA or cDNA prepared therefrom, wherein said portion comprises 5T4 RNA, and wherein amplification is performed qualitatively or quantitatively using oligonucleotide primers according to claim 1; and

c) detecting the amplified 5T4 RNA or cDNA product fragment.

4. A method of detecting 5T4 RNA in a bodily fluid from a human for detecting, diagnosing, monitoring, treating, or evaluating a neoplastic disease comprising cells that express 5T4 RNA, the method comprising the steps of:

a) extracting RNA from a bodily fluid;

McDonnell Boehnen Hulbert & Berghoff
300 South Wacker Drive, 32nd Floor
Chicago, Illinois 60606
(312) 913-0001

b) amplifying a portion of the extracted RNA or corresponding cDNA, wherein said portion comprises 5T4 RNA, and wherein amplification is performed qualitatively or quantitatively using oligonucleotide primers according to claim 1; and

c) detecting the amplified 5T4 RNA or corresponding cDNA product.

5. The method of claims 3 or 4, wherein the amplification in step (b) is performed by a RNA amplification method that amplifies the RNA directly or wherein the RNA is first reverse transcribed to cDNA whereby the cDNA is amplified, wherein the amplification method is reverse transcriptase polymerase chain reaction, ligase chain reaction, branched DNA signal amplification, amplifiable RNA reporters, Q-beta replication, transcription-based amplification, isothermal nucleic acid sequence-based amplification, self-sustained sequence replication assay, boomerang DNA amplification, strand displacement activation, or cycling probe technology.

6. The method of claims 3 and 4, wherein detection of amplified product in step (c) is performed using a detection method that is gel electrophoresis, capillary electrophoresis, ELISA detection including using biotinylated or other modified primers, labeled fluorescent or chromagenic probes, laser-induced fluorescence, Southern blot analysis, Northern blot analysis, electroluminescence, reverse blot detection, or high-performance liquid chromatography.

7. A method of identifying a human having 5T4 expressing cells or tissue, the method comprising the steps of:

a) extracting RNA from a bodily fluid of the human;

McDonnell Boehnen Hulbert & Berghoff
300 South Wacker Drive, 32nd Floor
Chicago, Illinois 60606
(312) 913-0001

b) amplifying a portion of the extracted RNA or the corresponding cDNA, wherein said portion comprises 5T4 RNA, and wherein amplification is performed qualitatively or quantitatively using oligonucleotide primers according to claim 1; and

c) detecting the amplified 5T4 RNA or corresponding cDNA product, whereby detection thereby identifies a human having 5T4 RNA expressing cells or tissue.

8. The method of claim 7, wherein the 5T4 expressing cells or tissue are those of a malignancy, or premalignancy, or carcinoma in situ.

9. The method of claim 8, wherein the malignancy is breast cancer, lung cancer or renal cancer.

10. The method of claim 7, wherein the human is at risk for developing a malignancy or premalignancy.

11. The method of claim 7, wherein the human is known to have a malignancy or premalignancy or carcinoma in situ.

12. The method of claims 3 or 4, wherein the human is a human at risk for a malignancy or premalignancy wherein the method comprises a screening method for malignancy or premalignancy, wherein 5T4 is expressed in said malignancy or premalignancy and wherein

McDonnell Boehnen Hulbert & Berghoff
300 South Wacker Drive, 32nd Floor
Chicago, Illinois 60606
(312) 913-0001

detection of 5T4 RNA in the plasma or serum fraction of blood of said human indicates that malignant or premalignant cells are present in the body of said human.

13. The method of claim 12, wherein the malignancy is breast cancer, lung cancer or renal cancer.

14. A method according to claims 3 or 4, further comprising the step of administering to the human a 5T4 directed therapy provided that the human is a human with cancer and 5T4 RNA is detected in the human's plasma or serum.

15. A method for selecting a human with cancer for a 5T4 directed therapy, the method comprising the steps of:

a) extracting RNA from cells or tissue from the human's cancer;

b) amplifying a portion of the extracted RNA or corresponding cDNA, wherein said portion comprises 5T4 RNA, and wherein amplification is performed qualitatively or quantitatively using oligonucleotide primers according to claim 1; and

c) detecting the amplified 5T4 RNA or corresponding cDNA product, whereby detection of the amplified 5T4 RNA or cDNA product selects the human with cancer for a 5T4 directed therapy.

16. The method of claim 15, wherein the amplification in step (b) is performed by an RNA amplification method that amplifies the RNA directly or wherein the RNA is first reverse

McDonnell Boehnen Hulbert & Berghoff
300 South Wacker Drive, 32nd Floor
Chicago, Illinois 60606
(312) 913-0001

transcribed to cDNA, whereby the cDNA is amplified, wherein the amplification method is reverse transcriptase polymerase chain reaction, ligase chain reaction, branched DNA signal amplification, amplifiable RNA reporters, Q-beta replication, transcription-based amplification, isothermal nucleic acid sequence based amplification, self-sustained sequence replication assays, boomerang DNA amplification, strand displacement activation, or cycling probe technology.

17. The method of claim 15, wherein detection of amplified product in step (c) is performed using a detection method that is gel electrophoresis, capillary electrophoresis, ELISA detection, including methods using biotinylated or otherwise modified primers, labeled fluorescent or chromogenic probes, laser-induced fluorescence, Southern blot analysis, Northern blot analysis, electrochemiluminescence, reverse dot blot detection, or high-performance liquid chromatography.

18. A method of detecting 5T4 RNA in blood plasma or serum from a woman for detecting, monitoring, or evaluating trophoblast tissue, wherein the trophoblast tissue expresses 5T4 RNA, the method comprising the steps of:

a) extracting RNA from blood plasma or serum;

b) amplifying a portion of the extracted RNA or cDNA prepared therefrom, wherein said portion comprises 5T4 RNA, and wherein amplification is performed qualitatively or quantitatively using oligonucleotide primers according to claim 1; and

c) detecting the amplified 5T4 RNA or cDNA product fragment.

McDonnell Boehnen Hulbert & Berghoff
300 South Wacker Drive, 32nd Floor
Chicago, Illinois 60606
(312) 913-0001

19. The method of claim 18, wherein the amplification in step (b) is performed by an RNA amplification method that amplifies the RNA directly or wherein the RNA is first reverse transcribed to cDNA, whereby the cDNA is amplified, wherein the amplification method is reverse transcriptase polymerase chain reaction, ligase chain reaction, branched DNA signal amplification, amplifiable RNA reporters, Q-beta replication, transcription-based amplification, isothermal nucleic acid sequence based amplification, self-sustained sequence replication assays, boomerang DNA amplification, strand displacement activation, or cycling probe technology.

20. The method of claim 18, wherein detection of amplified product in step (c) is performed using a detection method that is gel electrophoresis, capillary electrophoresis, ELISA detection, including methods using biotinylated or otherwise modified primers, labeled fluorescent or chromogenic probes, laser-induced fluorescence, Southern blot analysis, Northern blot analysis, electrochemiluminescence, reverse dot blot detection, or high-performance liquid chromatography.

21. A method of detecting trophoblast tissue in a woman post-partum or with an antecedent pregnancy, wherein trophoblast RNA is detected in the blood plasma or serum of the woman, and wherein the trophoblast RNA is expressed in trophoblast tissue, the method comprising the steps of:

a) extracting RNA from blood plasma or serum;

McDonnell Boehnen Hulbert & Berghoff
300 South Wacker Drive, 32nd Floor
Chicago, Illinois 60606
(312) 913-0001

b) amplifying a portion of the extracted RNA or cDNA prepared therefrom, wherein said portion comprises a trophoblast RNA, and wherein amplification is performed qualitatively or quantitatively using oligonucleotide primers according to claim 1; and

c) detecting the amplified trophoblast RNA or cDNA product fragment.

22. The method of claim 21, wherein the amplification in step (b) is performed by an RNA amplification method that amplifies the RNA directly or wherein the RNA is first reverse transcribed to cDNA, whereby the cDNA is amplified, wherein the amplification method is reverse transcriptase polymerase chain reaction, ligase chain reaction, branched DNA signal amplification, amplifiable RNA reporters, Q-beta replication, transcription-based amplification, isothermal nucleic acid sequence based amplification, self-sustained sequence replication assays, boomerang DNA amplification, strand displacement activation, or cycling probe technology.

23. The method of claim 21, wherein detection of amplified product in step (c) is performed using a detection method that is gel electrophoresis, capillary electrophoresis, ELISA detection, including methods using biotinylated or otherwise modified primers, labeled fluorescent or chromogenic probes, laser-induced fluorescence, Southern blot analysis, Northern blot analysis, electrochemiluminescence, reverse dot blot detection, or high-performance liquid chromatography.

McDonnell Boehnen Hulbert & Berghoff
300 South Wacker Drive, 32nd Floor
Chicago, Illinois 60606
(312) 913-0001

24. A method of monitoring the placenta during a pregnancy, wherein the placenta comprises 5T4 expressing cells or tissue, the method comprising the steps of:

a) extracting RNA from a bodily fluid of the human;

b) amplifying a portion of the extracted RNA or cDNA prepared therefrom, wherein said portion comprises 5T4 RNA and wherein amplification is performed qualitatively or quantitatively using oligonucleotide primers according to claim 1; and

c) detecting the amplified 5T4 RNA or cDNA product fragment.

25. The method of claim 24, wherein the bodily fluid is blood plasma or serum.

26. A method according to claim 24, wherein the woman has gestational trophoblastic disease, and wherein the disease is detected, monitored, or evaluated by detecting 5T4 RNA in a woman's blood plasma or serum.

27. The method of claim 24, wherein the amplification in step (b) is performed by an RNA amplification method that amplifies the RNA directly or wherein the RNA is first reverse transcribed to cDNA, whereby the cDNA is amplified, wherein the amplification method is reverse transcriptase polymerase chain reaction, ligase chain reaction, branched DNA signal amplification, amplifiable RNA reporters, Q-beta replication, transcription-based amplification, isothermal nucleic acid sequence based amplification, self-sustained sequence replication assays, boomerang DNA amplification, strand displacement activation, or cycling probe technology.

McDonnell Boehnen Hulbert & Berghoff
300 South Wacker Drive, 32nd Floor
Chicago, Illinois 60606
(312) 913-0001

28. The method of claim 24, wherein detection of amplified product in step (c) is performed using a detection method that is gel electrophoresis, capillary electrophoresis, ELISA detection, including methods using biotinylated or otherwise modified primers, labeled fluorescent or chromogenic probes, laser-induced fluorescence, Southern blot analysis, Northern blot analysis, electrochemiluminescence, reverse dot blot detection, or high-performance liquid chromatography.

McDonnell Boehnen Hulbert & Berghoff
300 South Wacker Drive, 32nd Floor
Chicago, Illinois 60606
(312) 913-0001